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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,949	07/06/2000	David M. Margolis	0184-0001CIP	6524

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EXAMINER
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GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/611,949	<b>Applicant(s)</b> MARGOLIS ET AL.	
	<b>Examiner</b> David Guzo	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**Election/Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a method of repressing HIV transcription in a human comprising administering a TRC comprising YY1 or a derivative or analog thereof, classified in class 514, subclass 2.
- II. Claim 1, drawn to a method of repressing HIV transcription in a human comprising administering a TRC comprising LSF or a derivative or analog thereof, classified in class 514, subclass 2.
- III. Claim 1, drawn to a method of repressing HIV transcription in a human comprising administering a TRC comprising HDAC1 or a derivative or analog thereof, classified in class 514, subclass 2.
- IV. Claims 2-3, 17-18, drawn to a method of repressing HIV transcription in a human comprising administering an agent that enhances binding of a YY1 or derivative or analog thereof to HDAC1, classified in class 514, subclass 2.
- V. Claims 2, 4, 17 and 19, drawn to a method of repressing HIV transcription in a human comprising administering an agent that enhances recruitment of HDAC1 or derivative or analog thereof by YY1 or a derivative or analog thereof, classified in class 514, subclass 2.
- VI. Claims 2, 5, 17 and 20, drawn to a method of repressing HIV transcription in a human comprising administering an agent that enhances the

enzymatic activity of HDAC1 or a derivative or analog thereof, classified in class 514, subclass 2.

- VII. Claims 2, 6-7, 17 and 21-22, drawn to a method of repressing HIV transcription in a human comprising administering an agent that enhances or up-regulates expression of HDAC or a derivative or analog thereof, classified in class 514, subclass 2.
- VIII. Claims 2, 8 and 16, drawn to a method of repressing HIV transcription in a human comprising administering an agent that comprises nucleic acid sequence(s) encoding YY1 or a derivative or analog thereof, classified in class 514, subclass 44.
- IX. Claims 2, 8 and 16, drawn to a method of repressing HIV transcription in a human comprising administering an agent that comprises nucleic acid sequence(s) encoding LSF or a derivative or analog thereof, classified in class 514, subclass 44.
- X. Claims 2, 8 and 16, drawn to a method of repressing HIV transcription in a human comprising administering an agent that comprises nucleic acid sequence(s) encoding HDAC1 or a derivative or analog thereof, classified in class 514, subclass 44.
- XI. Claims 9-10, drawn to a method of treating quiescent reservoirs of HIV infection in a human, comprising administering an agent that down-regulates expression of HDAC1 and subsequently with an antiretroviral agent, classified in class 514, subclass 2.

- XII. Claim 11, drawn to a method of treating or preventing latent HIV infection in a human, comprising administering an inhibitor of an HDAC1 recruiting activity of YY1 and one or more antiviral drugs, classified in class 514, subclass 2.
- XIII. Claims 12 and 23, drawn to an isolated purified composition comprising YY1, LSF and HDAC1 or derivatives or analogs thereof or a pharmaceutical composition comprising YY1, LSF and HDAC1, classified in class 530, subclass 350.
- XIV. Claim 13, drawn to a method for identifying agents having HIV transcription repressing activity, classified in class 435, subclass 7.1.
- XV. Claim 14, drawn to a method for modulating HIV transcription in a human, comprising administering an agent that modulates the histone structure of the RCS site of the HIV LTR, classified in class 514, subclass 2.
- XVI. Claim 15, drawn to a method for modulating HIV transcription in a human, comprising administering an agent that modulates the association between YY1 and HDAC1 at the RCS site of the HIV LTR, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve methods of repressing HIV transcription

in a human by administering different complexes, each comprising a distinct, unrelated, protein, i.e. YY1 vs. LSF vs. HDAC1. As each method uses a unrelated protein, each is patentably distinct and a search of all three would not be co-extensive and hence would be burdensome.

Inventions I, II, III and IV-XII, XIV-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve distinct, unrelated method steps involves administering unrelated agents which affect YYI, or LSF or HDAC1 or different biological properties of YYI, LSF or HDAC1 or a method for screening for agents having HIV transcription repressing activity, etc. A search of all of the methods would not be co-extensive and hence would be burdensome.

Inventions XIII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (composition comprising YY1, LSF and HDAC1) could be used to repress HIV transcription in a human. Claim 13 (Group XIV) is listed as being dependent from the composition of claim 11; however, claim 11 does not recite a composition. Claim 12 does recite a composition and hence it is assumed that applicants mean to recite claim 13 as depending from claim 12 rather than claim 11.

Inventions XIII and I-XII, XV-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups I-XII and XV-XVI do not require the particulars of the composition of Group XIII. While the recited methods use individual components of the composition recited in Group XIII, none of the claimed methods use all of the components of the composition as recited in Group XIII and none of the methods require all of the components of the composition of Group XIII.

Claims 2 and 17 link(s) inventions IV-IX and X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 2 and 17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See



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"Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
June 19, 2004

  
DAVID GUZO  
PRIMARY EXAMINER